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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/035,343  | 01/04/2002  | Daniel M. Cimbor     | 2318-290-II         | 1043             |
| 6449  | 7590        | 11/19/2003           | EXAMINER            |                  |
| ROTHWELL, FIGG, ERNST & MANBECK, P.C.<br>1425 K STREET, N.W.<br>SUITE 800<br>WASHINGTON, DC 20005 |             |                      | PROUTY, REBECCA E   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1652                |                  |

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,343

Applicant(s)

CIMBORA ET AL.

Examiner

Rebecca E. Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 162, 164-169, 171, 173-178, 180 and 182 is/are pending in the application.
- 4a) Of the above claim(s) 167, 168, 173, 174, 177, 180 and 182 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 162, 164-166, 169, 171, 175, 176 and 178 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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Claims 1-161, 163, 170, 172, 179, and 181 have been canceled. Claims 162, 164-169, 171, 173-178, 180, and 182 are still at issue and are present for examination.

Applicants' arguments filed on 8-22-03, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicants have amended Claim 162 such that it now recites subject matter within the elected invention. Claims 167-168, 173-174, 177, 180, and 182 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the response filed 4/11/03. Claims 162, 164-166, 169, 171, 175-176 and 178 are examined herein.

Applicant is advised that should claim 162 be found allowable, claim 171 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Claims 162, 164-166, 169, 171, 175-176 and 178 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of the terms IKKa, IKKb, IKKg, IKK-i, LDHM, EIF3S10, SLAP2, KIAA0614, SART-1, GBDR1, I-TRAF, NUMA1, SPA-1, and PN13730 is unclear as applicants have not clearly defined the meaning of these terms. Are these terms limited to the proteins encoded by the specific GenBank Accession Nos. recited in Table 15 and Example 2 (which it should be noted are indefinite in nature as they may be changed at any time) only and the sequence of PN13730 found on page 24 of the specification or do they include other proteins as well (for example species homologs, allelic variants and splice variants of the proteins encoded by these GenBank accession nos). If other proteins are encompassed it is unclear what features define proteins included within the scope of these names and what is not. As the scope of these terms is unclear the scope of fragments, fusion proteins and variants having 90% identity thereto recited in the claims is further unclear. Furthermore, the terms I-TRAF, EIF3S10 and GBDR1 are further unclear as the GenBank Accession Nos. recited in Table 15 appear to be incorrect or non-existent. Table 15 recites the GenBank Accession No U59683 for the protein I-TRAF,

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GenBank Accession No D50929 for the protein EIF3S10 and GenBank Accession No NM\_006318 for the protein GBDR1 however GenBank Accession No U59683 is drawn to the *Nicotiana tabacum* squalene synthase gene, GenBank Accession No D50929 is drawn to the human KIAA0139 gene which encodes a protein related to mouse centrosomin B and GenBank Accession No NM\_006318 no longer exists as it was removed at the submitter's request (see enclosed printouts). As such the meaning of these 3 proteins is even further unclear.

Claims 162, 164-166, 169, 171, and 174-175 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants negative limitation to exclude IKK-i/I-TRAF complexes specifically is new matter. Nowhere in the specification is the currently claimed genus of complexes contemplated. Furthermore, the amended claims filed 4/11/03 as well as the current claims include additional new matter as reciting a genus of complexes broader than disclosed in the

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original specification and claims. The current claims recite the following specific interactions (including interactions of fragments, variants and fusion proteins thereof) not disclosed in the original specification: IKKa/LDHM, IKKa/EIF3S10, IKKa/SLAP2, IKKa/KIAA0614, IKKa/SART-1, IKKa/I-TRAF, IKKa/NUMA1, IKKa/SPA-1, IKKb/I-TRAF, IKKb/NUMA1, IKKb/SPA-1, IKKg/LDHM, IKKg/EIF3S10, IKKg/SLAP2, IKKg/KIAA0614, IKKg/SART-1, IKKg/GBDR1, IKKg/NUMA1, IKKg/SPA-1, IKK-i/LDHM, IKK-i/EIF3S10, IKK-i/SLAP2, IKK-i/KIAA0614, IKK-i/SART-1, IKK-i/GBDR1.

Claims 162, 164-166, 169, 171, 175-176, and 178 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of selecting modulators of an interaction between an IKK-I homolog or variant as recited in the claims and I-TRAF, does not reasonably provide enablement for methods of selecting modulators of an interaction between any IKKa, IKKb, IKKg or IKK-i homolog as recited in the claims and any LDHM, EIF3S10, SLAP2, KIAA0614, SART-1, GBDR1, I-TRAF, NUMA1, SPA-1 OR PN13730. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants argue that whether or not the previously unknown

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protein-protein interactions and protein complexes discovered by the inventors are physiologically relevant or even are part of the NFκB signal transduction system is not germane to the issue of whether the pending claims are patentable. This is not persuasive because physiological relevance is necessary for knowing how to use something identified by the claimed methods. A method which identifies something which a skilled artisan would have no known use for has no patentable use itself. As such the specification has taught "how to use" only a small portion of the scope of the claimed methods. One of skill in the art would have no expectation that most compounds which would be selected by the claimed methods would be useful for modulating the NFκB signal transduction system or even as lead compounds for developing such compounds as there is no evidence that the binding of any of these pairs is in fact part of the NFκB signal transduction system and it would require undue experimentation to determine how to use compounds selected by the claimed methods which do not modulate a physiologically relevant interaction. While as applicants state, the claimed interactions **might** occur at the same binding surfaces as physiologically-relevant interactions of IKK-a, IKKb, IKKg and IKK-i (and thus they **might** serve as models of such interactions), the specification has failed to identify

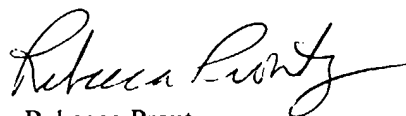
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any indication of which of the disclosed interactions this is in fact the case for. Applicants are reminded that patentable utility requires one to identify a use in **currently available form**. A patent is not a hunting license, it is not a reward for a search, but compensation for its successful conclusion.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Rebecca Prouty', with a stylized flourish at the end.

Rebecca Prouty  
Primary Examiner  
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